

## CHAPTER 8.7.

# INFECTION WITH FOOT AND MOUTH DISEASE VIRUS

## Article 8.7.1.

- 1) Many different species belonging to diverse taxonomic orders are known to be susceptible to *infection* with foot and mouth disease virus (FMDV). Their epidemiological significance depends upon the degree of susceptibility, the husbandry system, the density and extent of populations and the contacts between them. Amongst *Camelidae*, only Bactrian camels (*Camelus bactrianus*) are sufficiently susceptible to have potential for epidemiological significance. Dromedaries (*Camelus dromedarius*) are not susceptible to FMDV infection of dromedaries and while South American camelids are has not been shown considered to be of epidemiological significance.
- 2) For the purposes of the *Terrestrial Code*, foot and mouth disease (FMD) is defined as an *infection* of animals of the suborder *ruminantia* and of the family *suidae* of the order *Artiodactyla*, and *Camelus bactrianus* with any FMDV.
- 3) The following defines the occurrence of FMDV *infection*:
  - a) FMDV has been isolated from a sample from an animal listed in point 2; or
  - b) viral antigen or viral ribonucleic acid (RNA) specific to a serotype of FMDV has been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV; or
  - c) antibodies to structural or nonstructural proteins of FMDV, that are not a consequence of *vaccination*, have been identified in a sample from an animal listed in point 2, showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed or suspected outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV.
- 4) Transmission of FMDV in a vaccinated population is demonstrated by change in virological or serological evidence indicative of recent *infection*, even in the absence of clinical signs.
- 5) For the purposes of the *Terrestrial Code*, the *incubation period* of FMD is shall be 14 days.
- 6) *Infection* with FMDV can give rise to *disease* of variable severity and to FMDV transmission. FMDV may persist in the pharynx and associated lymph nodes of ruminants for a variable but limited period of time beyond 28 days. Such animals have been termed carriers. However, the only persistently infected species from which transmission of FMDV has been proven is the African buffalo (*Syncerus caffer*).
- 7) Theis chapter deals not only with the occurrence of clinical signs caused by FMDV, but also with the presence of FMDV *infection* and transmission, in the absence of clinical signs.
- 8) Standards for diagnostic tests and vaccines are described in the *Terrestrial Manual*.

## Article 8.7.2.

**FMD free country or zone where vaccination is not practised**

In defining a *zone* where *vaccination* is not practised the principles of Chapter 4.3. should be followed.



Susceptible animals in the FMD free country or *zone* where *vaccination* is not practised should be protected by the application of animal health biosecurity measures that prevent the entry of FMDV into the free country or *zone*. Taking into consideration physical or geographical barriers with any neighbouring infected country or *zone*, these measures may include a *protection zone*.

To qualify for inclusion in the existing list of FMD free countries or *zones* where *vaccination* is not practised, a Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting;
- 2) send a declaration to the OIE stating that during the past 12 months, within the proposed FMD free country or *zone*:
  - a) there has been no case of FMD;
  - b) no evidence of FMDV infection has been found;
  - e) no *vaccination* against FMD has been carried out;
- 3) supply documented evidence that for the past 12 months:
  - a) *surveillance* in accordance with Articles 8.7.40. to 8.7.42. has been implemented to detect clinical signs of FMD and show absence demonstrate no evidence of:
    - i) FMDV *infection* in non-unvaccinated animals;
    - ii) FMDV transmission in previously vaccinated animals when transition is made from the FMD free country or *zone* where *vaccination* is practised is seeking to become one to FMD-free country or zone where *vaccination* is not practised;
  - b) regulatory measures for the prevention and early detection of FMD have been implemented;
- 4) describe in detail and supply documented evidence that for the past 12 months the following have been properly implemented and supervised:
  - a) in the case of a FMD free *zone*, the boundaries of the proposed FMD free *zone*;
  - b) the boundaries and measures of a *protection zone*, if applicable;
  - c) the system for preventing the entry of FMDV into the proposed FMD free country or *zone*;
  - d) the control of the movement of susceptible animals, their *meat* and other products into the proposed FMD free country or *zone*, in particular the measures described in Articles 8.7.8., 8.7.9. and 8.7.12.;
  - e) no vaccinated animal has been introduced except in accordance with Articles 8.7.8. and 8.7.9.

The Member Country or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.



Provided the conditions of points 1 to 4 are fulfilled, the status of a country or zone will not be affected by applying official emergency vaccination of the to FMD susceptible animals in zoological collections in the face of a FMD threat identified by the Veterinary Authorities, provided that the following conditions are met:

- the zoological collection has a the primary purpose to of exhibiting animals or preserving rare species, has been identified, including the boundaries of the facility, and is included in the country's contingency plan for FMD;
- appropriate biosecurity measures are in place, including effective separation from other susceptible domestic populations or wildlife;
- the animals are identifiable as belonging to the collection and any movements can be traced;
- the vaccine used complies with the standards described in the Terrestrial Manual;
- vaccination is conducted under the supervision of the Veterinary Authority;
- the zoological collection is placed under surveillance for at least 12 months after vaccination.

In the event of the application for the status of a FMD free zone where vaccination is not practised to be assigned to a new zone adjacent to another FMD free zone where vaccination is not practised, it should be indicated stated if the new zone is being merged with the adjacent zone to become one enlarged zone. If the two zones remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate zones and particularly on the identification and the control of the movement of animals between the zones of the same status in accordance with Chapter 4.3.

#### Article 8.7.3.

#### **FMD free country or zone where vaccination is practised**

In defining a zone where vaccination is practised the principles of Chapter 4.3. should be followed.

Susceptible animals in the FMD free country or zone where vaccination is practised should be protected by the application of animal health biosecurity measures that prevent the entry of FMDV into the free country or zone. Taking into consideration physical or geographical barriers with any neighbouring infected country or zone, these measures may include a protection zone.

Based on the epidemiology of FMD in the country, it may be decided to vaccinate only a defined subpopulation subpopulation comprised of certain species or other subsets of the total susceptible population.

To qualify for inclusion in the list of FMD free countries or zones where vaccination is practised, a Member Country should:

- 1) have a record of regular and prompt animal disease reporting;
- 2) send a declaration to the OIE stating that, based on the surveillance described in point 3, within the proposed FMD free country or zone:
  - a) there has been no case of FMD during the past two years;
  - b) there has been no evidence of FMDV transmission during the past 12 months;
- 3) supply documented evidence that:
  - a) surveillance in accordance with Articles 8.7.40. to 8.7.42. has been implemented to detect clinical signs of FMD and show absence demonstrate no evidence of:
    - i) FMDV infection in non-unvaccinated animals;
    - ii) FMDV transmission in vaccinated animals;



- b) regulatory measures for the prevention and early detection of FMD have been implemented;
  - c) compulsory systematic *vaccination* in the target population has been carried out to achieve adequate *vaccination* coverage and population immunity;
  - d) ~~the *vaccination* has been carried out following~~ *e-used* ~~complies with the standards described in the *Terrestrial Manual*, including~~ appropriate vaccine strain selection;
- 4) describe in detail and supply documented evidence that the following have been properly implemented and supervised:
- a) in case of FMD free *zone*, the boundaries of the proposed FMD free *zone*;
  - b) the boundaries and measures of a *protection zone*, if applicable;
  - c) the system for preventing the entry of FMDV into the proposed FMD free country or *zone*, in particular the measures described in Articles 8.7.8., 8.7.9. and 8.7.12.;
  - d) the control of the movement of susceptible animals and their products into the proposed FMD free country or *zone*.

The Member Country or the proposed free *zone* will be included in the list of FMD free countries or *zones* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Retention on the list requires that the information in points 2, 3 and 4 above be re-submitted annually and changes in the epidemiological situation or other significant events including those relevant to points 3b) and 4 should be reported to the OIE according to the requirements in Chapter 1.1.

If a Member Country that meets the requirements of a FMD free country or *zone* where *vaccination* is practised wishes to change its status to FMD free country or *zone* where *vaccination* is not practised, it should notify the OIE in advance of the intended date of cessation of *vaccination* and apply for the new status within 24 months *of the cessation*. The status of this country or *zone* remains unchanged until compliance with Article 8.7.2. is approved by the OIE. If the dossier for the new status is not provided within 24 months then the status of the country or *zone* as being free with *vaccination* will be suspended. If the country does not comply with requirements of Article 8.7.2., evidence should be provided within three months that it complies with Article 8.7.3. Otherwise the status will be withdrawn.

In the event of the application for the status of a FMD free *zone* where *vaccination* is practised to be assigned to a new *zone* adjacent to another FMD free *zone* where *vaccination* is practised, it should be *indicated stated* if the new *zone* is being merged with the adjacent *zone* to become one enlarged *zone*. If the two *zones* remain separate, details should be provided on the control measures to be applied for the maintenance of the status of the separate *zones* and particularly on the identification and the control of the movement of *animals* between the *zones* of the same status in accordance with Chapter 4.3.

#### Article 8.7.4.

##### **FMD free compartment**

A FMD free *compartment* can be established in either a FMD free country or *zone* or in an infected country or *zone*. In defining such a *compartment* the principles of Chapters 4.3. and 4.4. should be followed. Susceptible animals in the FMD free *compartment* should be separated from any other susceptible animals by the application of an effective biosecurity management system.

A Member Country wishing to establish a FMD free *compartment* should:

- 1) have a record of regular and prompt animal *disease* reporting and, if not FMD free, have an *official control programme* and a *surveillance* system for FMD in place according to Articles 8.7.40. to 8.7.42. that allows knowledge of the prevalence, distribution and characteristics of FMD in the country or *zone*;
- 2) declare for the FMD free *compartment* that:



- a) there has been no case of FMD during the past 12 months;
  - b) no evidence of FMDV *infection* has been found during the past 12 months;
  - c) *vaccination* against FMD is prohibited;
  - d) no animal vaccinated against FMD within the past 12 months is in the *compartment*;
  - e) animals, semen, embryos and animal products **should** **may** only enter the *compartment* in accordance with relevant articles in this chapter;
  - f) documented evidence shows that *surveillance* in accordance with Articles 8.7.40. to 8.7.42. is in operation;
  - g) an *animal identification* and traceability system in accordance with Chapters 4.1. and 4.2. is in place;
- 3) describe in detail:
- a) the animal *subpopulation* in the *compartment*;
  - b) the *biosecurity plan* to mitigate the risks identified by the *surveillance* carried out according to point 1.

The *compartment* should be approved by the *Veterinary Authority*. The first approval should only be granted when no case of FMD has occurred within a ten-kilometre radius of the *compartment* during the past three months.

#### Article 8.7.5.

#### **FMD infected country or zone**

For the purposes of this chapter, a FMD infected country or *zone* is one that does not fulfil the requirements to qualify as either FMD free where *vaccination* is not practised or FMD free where *vaccination* is practised.

#### Article 8.7.6.

#### **Establishment of a containment zone within a FMD free country or zone**

In the event of limited *outbreaks* within a FMD free country or *zone*, including within a *protection zone*, with or without *vaccination*, a single *containment zone*, which includes all *outbreaks*, may be established for the purpose of minimising the impact on the entire country or *zone*.

For this to be achieved and for the Member Country to take full advantage of this process, the *Veterinary Authority* should submit as soon as possible to the OIE, in support of the application, documented evidence that:



- 1) on suspicion, a strict standstill of animal movements has been imposed on the suspected establishments and in the country or zone animal movement control has been imposed in the country or zone; and effective controls on the movement of other *commodities* mentioned in this chapter are in place;
- 2) on confirmation, an additional standstill of susceptible animals has been imposed in the entire containment zone and the movement controls described in point 1 have been reinforced;
- 3) the definitive boundaries of the *containment zone* may only be have been established once after an epidemiological investigation (trace-back, trace-forward) has demonstrated that the *outbreaks* are epidemiologically related and limited in number and geographic distribution;
- 4) investigations into the likely source of the *outbreak* have been carried out;
- 5) a *stamping-out policy*, with or without the use of emergency *vaccination*, has been applied;
- 6) no new cases have been found in the *containment zone* within a minimum of two *incubation periods* as defined in Article 8.7.1. after the application of a *stamping-out policy* to the last detected case;
- 7) the susceptible domestic and *captive wild* animal populations within the *containment zone* are clearly identifiable as belonging to the *containment zone*;
- 8) *surveillance* in accordance with Articles 8.7.40.to 8.7.42. is in place in the *containment zone* and in the rest of the country or *zone*;
- 9) animal health measures that prevent the spread of FMDV to the rest of the country or *zone*, taking into consideration physical and geographical barriers, are in place.

The free status of the areas outside the *containment zone* is suspended while the *containment zone* is being established. The free status of these areas may be reinstated irrespective of the provisions of Article 8.7.7., once the *containment zone* has been approved, by the OIE as complying with points 1 to 9 above. *Commodities* from susceptible animals for *international trade* should be identified as to their origin, either from inside or outside the *containment zone*.

In the event of recurrence of FMDV infection in unvaccinated animals or FMDV transmission in vaccinated animals in the *containment zone*, the approval of the *containment zone* is withdrawn, and the FMD status of the whole country or *zone* is suspended until the relevant requirements of Article 8.7.7. are fulfilled.

The recovery of the FMD free status of the *containment zone* should be achieved within 12 months of its approval and follow the provisions of Article 8.7.7.

#### Article 8.7.7.

##### Recovery of free status (see Figures 1 and 2)

- 1) When a FMD case occurs in a FMD free country or *zone* where *vaccination* is not practised, one of the following waiting periods is required to regain this free status:
  - a) three months after the disposal of the last case animal killed where a *stamping-out policy*, without emergency *vaccination*, and *surveillance* are applied in accordance with Articles 8.7.40. to 8.7.42.; or
  - b) three months after the disposal of the last case animal killed or the *slaughter* of all vaccinated animals, whichever occurred last, where a *stamping-out policy*, emergency *vaccination* and *surveillance* in the remaining animals are applied are applied in accordance with Articles 8.7. 40. to 8.7.42.



- c) six months after the disposal of the last case animal killed or the last *vaccination* whichever occurred last, where a *stamping-out policy*, emergency *vaccination* not followed by the slaughtering of all vaccinated animals, and *surveillance* are applied in accordance with Articles 8.7.40. to 8.7.42. are applied. However, this requires a serological survey based on the detection of antibodies to nonstructural proteins of FMDV to demonstrate the absence no evidence of infection in the remaining vaccinated population. This period can be reduced to three months if effectiveness of vaccination using vaccine compliant with the Terrestrial Manual is demonstrated and additional serological surveillance for antibodies to nonstructural proteins is carried out in all vaccinated herds. This includes sampling all vaccinated ruminants and their non-vaccinated offspring, and a representative number of animals of other species, based on an acceptable level of confidence.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is not practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

The time periods in points 1a) to 1c) are not affected if official emergency *vaccination* of zoological collections has been carried out following the relevant provisions of Article 8.7.2.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.7.2. applies.

- 2) When a FMD *case* occurs in a FMD free country or *zone* where *vaccination* is not practised, the following waiting period is required to gain the status of FMD free country or *zone* where *vaccination* is practised: three six months after the disposal of the last case animal killed where a *stamping-out policy* has been applied and a continued *vaccination* policy has been adopted, provided that *surveillance* is applied in accordance with Articles 8.7.40. to 8.7.42., and a serological survey based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence no evidence of FMDV transmission.

The country or *zone* can gain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

Where a *stamping-out policy* is not practised, the above waiting periods do not apply, and Article 8.7.3. applies.

- 3) When a case of FMD outbreak or FMDV transmission occurs in a FMD free country or *zone* where *vaccination* is practised, one of the following waiting periods is required to regain this free status:
- a) six months after the disposal of the last case animal killed where a *stamping-out policy*, with emergency *vaccination*, and *surveillance* in accordance with Articles 8.7.40. to 8.7.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence no evidence of virus transmission; or
  - b) 12 months after the detection of the last *case* where a *stamping-out policy* is not applied, but where emergency *vaccination* and *surveillance* in accordance with Articles 8.7.40. to 8.7.42. are applied, provided that serological *surveillance* based on the detection of antibodies to nonstructural proteins of FMDV demonstrates the absence no evidence of virus transmission.

Where an emergency *vaccination* is not applied, the above waiting periods do not apply, and Article 8.7.3. applies.

The country or *zone* will regain the status of FMD free country or *zone* where *vaccination* is practised only after the submitted evidence, based on the provisions of Article 1.6.6., has been accepted by the OIE.

- 4) When a FMD *case* occurs in a FMD free *compartment*, Article 8.7.4. applies.
- 5) Member Countries applying for the recovery of status should do so only when the respective requirements for the recovery of status are met. When a *containment zone* has been established, the



restrictions within the *containment zone* should be lifted in accordance with the requirements of this article only when the *disease* has been successfully eradicated within the *containment zone*.

For Member Countries not applying for recovery within 24 months after suspension, the provisions of Article 8.7.2., Article 8.7.3. or Article 8.7.4. apply.

#### Article 8.7.8.

Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (~~where~~ whether vaccination ~~either is or is not~~ is practised ~~or not~~)

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the *infected zone* if transported directly to *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

- 1) no FMD susceptible animal has been introduced into the *establishment* of origin and no animal in the *establishment* of origin has shown clinical signs of FMD for at least 30 days prior to movement;
- 2) the animals were kept in the *establishment* of origin for at least three months prior to movement;
- 3) FMD has not occurred within a 10 kilometre radius of the *establishment* of origin for at least four weeks prior to movement;
- 4) the animals should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 5) such a *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *infected zone*;
- 6) *vehicles* and the *slaughterhouse/abattoir* should be subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* with no evidence of FMD, and the *meat* derived from them treated according to point 2 of Article 8.7.22. or Article 8.7.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.7.31. to 8.7.38 in order such a way as to destroy any residual FMDV potentially present in accordance with Articles 8.7.31. to 8.7.38.

#### Article 8.7.9.

Direct transfer of FMD susceptible animals from a containment zone for slaughter in a free zone (~~where~~ whether vaccination ~~either is or is not~~ is practised ~~or not~~)

In order not to jeopardise the status of a free zone, FMD susceptible animals should only leave the *containment zone* if transported directly to *slaughter* in the nearest designated *slaughterhouse/abattoir* under the following conditions:

- 1) the *containment zone* has been officially established according to the requirements in Article 8.7.6.;
- 2) the animals should be transported under the supervision of the *Veterinary Authority* in a *vehicle*, which was cleansed and disinfected before *loading*, directly from the *establishment* of origin to the *slaughterhouse/abattoir* without coming into contact with other susceptible animals;
- 3) such an *slaughterhouse/abattoir* is not approved for the export of *fresh meat* during the time it is handling the *meat* of animals from the *containment zone*;



- 4) *vehicles* and the slaughterhouse/abattoir should be subjected to thorough cleansing and *disinfection* immediately after use.

The animals should have been subjected to ante- and post-mortem inspection for FMD, with favourable results, within 24 hours before and after *slaughter* with no evidence of FMD and the *meat* derived from them treated according to point 2 of Article 8.7.22. or Article 8.7.23. Other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.7.31. to 8.7.38 in order such a way as to destroy any residual FMDV potentially present in accordance with Articles 8.7.31. to 8.7.38.

#### Article 8.7.10.

**Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**

##### For FMD susceptible animals

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD free country or *zone* where *vaccination* is not practised or a FMD free *compartment*;
- 3) if transiting an *infected zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

#### Article 8.7.11.

**Recommendations for importation from FMD free countries or zones where vaccination is practised**

##### For domestic ruminants and pigs

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the animals:

- 1) showed no clinical sign of FMD on the day of shipment;
- 2) were kept since birth or for at least the past three months in a FMD free country or *zone* where *vaccination* is practised;
- 3) were subjected to a test for FMD with negative results;
- 4) if transiting an *infected zone*, were not exposed to any source of FMDV during transportation to the *place of shipment*.

#### Article 8.7.12.

**Recommendations for importation from FMD infected countries or zones where an official control programme exists**

##### For domestic ruminants and pigs

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the animals showed no clinical sign of FMD on the day of shipment;
- 2) prior to isolation, the animals were kept in the *establishment* of origin:
  - a) since birth, or
  - b) for the past 30 days, or since birth if younger than 30 days, if a *stamping-out policy* is applied to control FMD in force in the *exporting country or zone*, or
  - be) for the past three months, or since birth if younger than three months if a *stamping-out policy* is not applied to control FMD in force in the *exporting country or zone*,



- 3) **and that** FMD has not occurred within the *establishment* of origin for the relevant period as defined in points 2 a) and 2 b) above;
- 4) the animals were isolated in an *establishment* for the 30 days prior to shipment, and all animals in isolation were subjected to diagnostic virological and serological tests for evidence of FMDV with negative results on samples collected at least 28 days after the start of isolation period, and that FMD did not occur within a 10 kilometre radius of the *establishment* during that period, **or the establishment is a quarantine station**;
- 5) the animals were not exposed to any source of FMDV during their transportation from the *establishment* to the *place of shipment*.

## Article 8.7.13.

**Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**For fresh semen of domestic ruminants and pigs

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor **animals males**:
  - a) showed no clinical sign of FMD on the day of collection of the semen;
  - b) were kept for at least three months prior to collection in a FMD free country or **zone** where *vaccination* is not practised or FMD free *compartments*;
  - c) were kept in an *artificial insemination centre* where none of the animals had a history of *infection with FMDV*;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

## Article 8.7.14.

**Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**For frozen semen of domestic ruminants and pigs

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor **animals males**:
  - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
  - b) were kept for at least three months prior to collection in a FMD free country or *zone* where *vaccination* is not practised or FMD free *compartments*;
- 2) the semen was collected, processed and stored in conformity with the provisions of Chapters 4.5. and 4.6.

## Article 8.7.15.

**Recommendations for importation from FMD free countries or zones where vaccination is practised**For frozen semen of domestic ruminants and pigs



*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor **animals males**:
  - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
  - b) were kept for at least three months prior to collection in a FMD free country or *zone* where *vaccination* is practised;
  - c) either
    - i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six months prior to collection, unless protective immunity has been **proven demonstrated** for more than six months;
    - or
    - ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
  - a) was collected, processed and stored in accordance with the provisions of Chapters 4.5. and 4.6.;
  - b) was stored in the country of origin for a period of at least one month following collection, and during this period no animal on the *establishment* where the donor animals were kept showed any sign of FMD.

#### Article 8.7.16.

#### **Recommendations for importation from FMD infected countries or zones**

##### For frozen semen of domestic ruminants and pigs

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor **animals males**:
  - a) showed no clinical sign of FMD on the day of collection of the semen and for the following 30 days;
  - b) were kept in an *artificial insemination centre* where no animal had been added in the 30 days before collection, and that FMD has not occurred within a 10 kilometre radius of the *artificial insemination centre* for the 30 days before and after collection;
  - c) either
    - i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six month prior to collection, unless protective immunity has been **proven demonstrated** for more than six months;
    - or
    - ii) were subjected, not less than 21 days after collection of the semen, to tests for antibodies against FMDV, with negative results;
- 2) the semen:
  - a) was collected, processed and stored in accordance with the provisions of Chapters 4.5. and 4.6.;
  - b) was subjected, with negative results, to a test for evidence of FMDV if the donor **animal male** has been vaccinated within the 12 months prior to collection;



- c) was stored in the country of origin for a period of at least one month following collection, and that during this period no animal on the *establishment* where the donor **animals** **males** were kept showed any sign of FMD.

Article 8.7.17.

**Recommendations for the importation of *in vivo* derived embryos of cattle**

Irrespective of the FMD status of the *exporting country, zone or compartment*, *Veterinary Authorities* should authorise without restriction on account of FMD the import or transit through their territory of *in vivo* derived embryos of cattle subject to the presentation of an *international veterinary certificate* attesting that the embryos were collected, processed and stored in accordance with the provisions of Chapters 4.7. and 4.9., as relevant.

Article 8.7.18.

**Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**

For *in vitro* produced embryos of cattle

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
  - a) showed no clinical sign of FMD at the time of collection of the oocytes;
  - b) were kept for at least three months prior to collection in a FMD free country or zones where *vaccination* is not practised or FMD free *compartments*;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.7.13., 8.7.14., 8.7.15. or 8.7.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7.19.

**Recommendations for importation from FMD free countries or zones where vaccination is practised**

For *in vitro* produced embryos of cattle

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the donor females:
    - a) showed no clinical sign of FMD at the time of collection of the oocytes;
    - b) were kept for at least three months prior to collection in a FMD free country or zones where *vaccination* is practised;
    - c) either
      - i) have been vaccinated at least twice, with the last *vaccination* not less than one month and not more than six months prior to collection, unless protective immunity has been **proven demonstrated** for more than six months;
- or



- ii) were subjected, not less than 21 days after collection, to tests for antibodies against FMDV, with negative results;
- 2) fertilisation was achieved with semen meeting the conditions referred to in Articles 8.7.13., 8.7.14., 8.7.15. or 8.7.16., as relevant;
- 3) the oocytes were collected, and the embryos were processed and stored in accordance with the provisions of Chapters 4.8. and 4.9., as relevant.

Article 8.7.20.

**Recommendations for importation from FMD free countries or zones where vaccination is not practised or FMD free compartments**

For fresh meat or meat products of FMD susceptible animals

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which:

- 1) have been kept in a FMD free country or **zones** where *vaccination* is not practised or FMD free **compartments**, or which have been imported in accordance with Article 8.7.10., Article 8.7.11. or Article 8.7.12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections with favourable results.

Article 8.7.21.

**Recommendations for importation from FMD free countries, or zones where vaccination is practised**

For fresh meat and meat products of ruminants and pigs

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat* comes from animals which:

- 1) have been kept in the FMD free country or *zone* where *vaccination* is practised, or which have been imported in accordance with Article 8.7. 10., Article 8.7. 11. or Article 8.7. 12.;
- 2) have been slaughtered in an approved *slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;
- 3) for ruminants the head, including the pharynx, tongue and associated lymph nodes, has been excluded from the shipment.

Article 8.7.22.

**Recommendations for importation from FMD infected countries or zones where an official control programme exists**

For fresh meat of cattle and water buffaloes (*Bubalus bubalis*) (excluding feet, head and viscera)

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the entire consignment of *meat*:

- 1) comes from animals which:
  - a) have remained, for at least three months prior to *slaughter*, in a *zone* of the *exporting country* where cattle and water buffaloes are regularly vaccinated against FMD and where an *official control programme* is in operation;



- b) have been vaccinated at least twice with the last *vaccination* not more than six months, unless protective immunity has been ~~proven~~ demonstrated for more than six months, and not less than one month prior to *slaughter*;
  - c) were kept for the past 30 days in an *establishment*, and that FMD has not occurred within a 10 kilometre radius of the *establishment* during that period, or the establishment is a quarantine station;
  - d) have been transported, in a *vehicle* which was cleansed and disinfected before the cattle and water buffaloes were loaded, directly from the *establishment* of origin or quarantine station to the approved *slaughterhouse/abattoir* without coming into contact with other *animals* which do not fulfil the required conditions for export;
  - e) have been slaughtered in an approved *slaughterhouse/abattoir*:
    - i) which is officially designated for export;
    - ii) in which no FMD has been detected during the period between the last *disinfection* carried out before *slaughter* and the shipment for export has been dispatched;
  - f) have been subjected to ante- and post-mortem inspections ~~for FMD with favourable results~~ within 24 hours before and after *slaughter* with no evidence of FMD;
- 2) comes from deboned carcasses:
- a) from which the major lymphatic nodes have been removed;
  - b) which, prior to deboning, have been submitted to maturation at a temperature above greater than + 2°C for a minimum period of 24 hours following *slaughter* and in which the pH value was below less than 6.0 when tested in the middle of both the longissimus dorsi muscle.

#### Article 8.7.23.

#### Recommendations for importation from FMD infected countries or zones

##### For meat products of FMD susceptible animals

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) the entire consignment of *meat products* come from animals which have been slaughtered in an *approved slaughterhouse/abattoir* and have been subjected to ante- and post-mortem inspections for FMD with favourable results;
- 2) the *meat products* have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.7.31.;
- 3) the necessary precautions were taken after processing to avoid contact of the *meat products* with any potential source of FMDV.

#### Article 8.7.24.

#### Recommendations for importation from FMD free countries or zones where vaccination either is or is not practised or FMD free compartments

##### For milk and milk products intended for human consumption and for products of animal origin (from FMD susceptible animals) intended for use in animal feeding or for agricultural or industrial use

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products come from animals which have been kept in a FMD free country, *zone* or *compartment*, or which have been imported in accordance with Article 8.7.10., Article 8.7.11. or Article 8.7.12.

#### Article 8.7.25.

#### Recommendations for importation from FMD infected countries or zones where an official control programme exists



#### For milk and milk products

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these products:
  - a) originate from *establishments* which were not infected or suspected of being infected with FMD at the time of *milk* collection;
  - b) have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Article 8.7.35. and in Article 8.7.36.;
- 2) the necessary precautions were taken after processing to avoid contact of the products with any potential source of FMDV.

Article 8.7.26.

#### **Recommendations for importation from FMD infected countries**

##### For blood-meal and meat-meals from FMD susceptible animals

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that the manufacturing method for these products included heating to a minimum core temperature of 70°C for at least 30 minutes.

Article 8.7.27.

#### **Recommendations for importation from FMD infected countries**

##### For wool, hair, bristles, raw hides and skins from FMD susceptible animals

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that:

- 1) these products have been processed to ensure the destruction of FMDV in accordance with one of the procedures in Articles 8.7.32., 8.7.33. and 8.7.34.;
- 2) the necessary precautions were taken after collection or processing to avoid contact of the products with any potential source of FMDV.

*Veterinary Authorities* should authorise, without restriction, the import or transit through their territory of semi-processed hides and skins (limed hides, pickled pelts, and semi-processed leather such as wet blue and crust leather), provided that these products have been submitted to the usual chemical and mechanical processes in use in the tanning industry.

Article 8.7.28.

#### **Recommendations for importation from FMD infected countries or zones**

##### For straw and forage

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these *commodities*:

- 1) are free of grossly identifiable contamination with material of animal origin;
- 2) have been subjected to one of the following treatments, which, in the case of material sent in bales, has been shown to penetrate to the centre of the bale:
  - a) either to the action of steam in a closed chamber such that the centre of the bales has reached a minimum temperature of 80°C for at least ten minutes,
  - b) or to the action of formalin fumes (formaldehyde gas) produced by its commercial solution at 35–40 percent in a chamber kept closed for at least eight hours and at a minimum temperature of 19°C;



OR

- 3) have been kept in bond for at least four months before being released for export.

Article 8.7.29.

**Recommendations for importation from FMD free countries or zones where vaccination either is or is not practised**

For skins and trophies derived from FMD susceptible wildlife

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products are derived from animals that have been killed in such a country or zone or which have been imported from a country, zone, or compartment free from FMD.

Article 8.7.30.

**Recommendations for importation from FMD infected countries or zones**

For skins and trophies derived from FMD susceptible wildlife

*Veterinary Authorities* should require the presentation of an *international veterinary certificate* attesting that these products have been processed to ensure the destruction of FMDV in accordance with the procedures in Article 8.7.37.

Article 8.7.31.

**Procedures for the inactivation of FMDV in meat and meat products**

For the inactivation of FMDV present in *meat* and *meat products*, one of the following procedures should be used:

1. Canning

*Meat* and *meat products* are subjected to heat treatment in a hermetically sealed container to reach an internal core temperature of at least 70°C for a minimum of 30 minutes or to any equivalent treatment which has been demonstrated to inactivate FMDV.

2. Thorough cooking

*Meat*, previously deboned and defatted, and *meat products* are subjected to a heat treatment that results in a core temperature of at least 70°C or more for a minimum of 30 minutes.

After cooking, they should be packed and handled in such a way they are not exposed to a source of FMDV.

3. Drying after salting

When *rigor mortis* is complete, the *meat* is deboned, treated with salt (NaCl) and completely dried. It should not deteriorate at ambient temperature.

'Completely dried' is defined as a moisture protein ratio between water and protein that is not greater than 2.25:1 or a water activity (Aw) that is not greater than 0.85.

Article 8.7.32.

**Procedures for the inactivation of FMDV in wool and hair**

For the inactivation of FMDV present in wool and hair for industrial use, one of the following procedures should be used:

- 1) industrial washing, which consists of the immersion of the wool in a series of baths of water, soap and sodium hydroxide (soda) or potassium hydroxide (potash);



- 2) chemical depilation by means of slaked lime or sodium sulphide;
- 3) fumigation with formaldehyde in a hermetically sealed chamber for at least 24 hours;
- 4) industrial scouring which consists of the immersion of wool in a water-soluble detergent held at 60–70°C;
- 5) storage of wool at 4°C for four months, 18°C for four weeks or 37°C for eight days.

#### Article 8.7.33.

#### **Procedures for the inactivation of FMDV in bristles**

For the inactivation of FMDV present in bristles for industrial use, one of the following procedures should be used:

- 1) boiling for at least one hour; or
- 2) immersion for at least 24 hours in a 1 % aqueous solution of formaldehyde.

#### Article 8.7.34.

#### **Procedures for the inactivation of FMDV in raw hides and skins**

For the inactivation of FMDV present in raw hides and skins for industrial use, the following procedure should be used: treatment for at least 28 days with salt (NaCl) containing 2 % sodium carbonate (Na<sub>2</sub>CO<sub>3</sub>).

#### Article 8.7.35.

#### **Procedures for the inactivation of FMDV in milk and cream for human consumption**

For the inactivation of FMDV present in *milk* and cream for human consumption, one of the following procedures should be used:

- 1) a process applying a minimum temperature of 132°C for at least one second (ultra-high temperature [UHT]), or
- 2) if the *milk* has a pH less than 7.0, a process applying a minimum temperature of 72°C for at least 15 seconds (high temperature – short time pasteurisation [HTST]), or
- 3) if the *milk* has a pH of 7.0 or greater, the HTST process applied twice.



## Article 8.7.36.

**Procedures for the inactivation of FMDV in milk for animal consumption**

For the inactivation of FMDV present in *milk* for animal consumption, one of the following procedures should be used:

- 1) the HTST process applied twice; or
- 2) HTST combined with another physical treatment, e.g. maintaining a pH 6 for at least one hour or additional heating to at least 72°C combined with desiccation; or
- 3) UHT combined with another physical treatment referred to in point 2 above.

## Article 8.7.37

**Procedures for the inactivation of FMDV in skins and trophies from ~~wild animals~~ wildlife susceptible to the disease**

For the inactivation of FMDV present in skins and trophies from *wild animals* susceptible to FMD, one of the following procedures should be used prior to complete taxidermal treatment:

- 1) boiling in water for an appropriate time so as to ensure that any matter other than bone, horns, hooves, claws, antlers or teeth is removed; or
- 2) gamma irradiation at a dose of at least 20 kiloGray at room temperature (20°C or higher); or
- 3) soaking, with agitation, in a 4 % (weight/volume) solution of sodium carbonate ( $\text{Na}_2\text{CO}_3$ ) maintained at pH 11.5 or greater for at least 48 hours; or
- 4) soaking, with agitation, in a formic acid solution (100 kg salt [ $\text{NaCl}$ ] and 12 kg formic acid per 1,000 litres water) maintained at below pH less than 3.0 for at least 48 hours; wetting and dressing agents may be added; or
- 5) in the case of raw hides, treating for at least 28 days with salt ( $\text{NaCl}$ ) containing 2 % sodium carbonate ( $\text{Na}_2\text{CO}_3$ ).

## Article 8.7.38.

**Procedures for the inactivation of FMDV in casings of ruminants and pigs**

For the inactivation of FMDV present in casings of ruminants and pigs, the following procedures should be used: treating for at least 30 days either with dry salt ( $\text{NaCl}$ ) or with saturated brine ( $\text{NaCl}$ ,  $a_w < 0.80$ ), or with phosphate supplemented salt containing 86.5 %  $\text{NaCl}$ , 10.7 %  $\text{Na}_2\text{HPO}_4$  and 2.8 %  $\text{Na}_3\text{PO}_4$  (weight/weight/weight), either dry or as a saturated brine ( $a_w < 0.80$ ), and kept at a temperature of greater than 12°C during this entire period.

## Article 8.7.39.

**OIE endorsed official control programme for FMD**

The overall objective of an OIE endorsed *official control programme* for FMD is for countries to progressively improve the situation and eventually attain FMD-free status. The *official control programme* should be applicable to the entire country even if certain measures are directed only towards defined *subpopulations* only.

Member Countries may, on a voluntary basis, apply for endorsement of their *official control programme* for FMD when they have implemented measures in accordance with this article.



For a Member Country's *official control programme* for FMD to be endorsed by the OIE, the Member Country should:

- 1) have a record of regular and prompt animal *disease* reporting according to the requirements in Chapter 1.1.;
- 2) submit documented evidence of the capacity of the *Veterinary Services* to control FMD; one way of providing this evidence is through the OIE PVS Pathway;
- 3) submit a detailed plan of the programme to control and eventually eradicate FMD in the country or *zone* including:
  - a) the timeline;
  - b) the performance indicators for assessing the efficacy of the control measures to be implemented;
  - c) documentation indicating that the *official control programme* for FMD is applicable to the entire country;
- 4) submit a dossier on the epidemiology of FMD in the country describing the following:
  - a) the general epidemiology in the country highlighting the current knowledge and gaps and the progress that has been made in controlling FMD;
  - b) the measures implemented to prevent introduction of *infection*, the rapid detection of, and response to, all FMD *outbreaks* in order to reduce the incidence of FMD *outbreaks* and to eliminate FMDV transmission in at least one *zone* in the country;
  - c) the main livestock production systems and movement patterns of FMD susceptible animals and their products within and into the country;
- 5) submit evidence that FMD *surveillance* is in place:
  - a) taking into account provisions in Chapter 1.4. and the provisions on *surveillance* of this chapter;
  - b) have diagnostic capability and procedures, including regular submission of samples to a *laboratory* that carries out diagnosis and further characterisation of strains;
- 6) where *vaccination* is practised as a part of the *official control programme* for FMD, provide:
  - a) evidence (such as copies of legislation) that *vaccination* of selected populations is compulsory;
  - b) detailed information on *vaccination* campaigns, in particular on:
    - i) target populations for *vaccination*;
    - ii) monitoring of *vaccination* coverage, including serological monitoring of population immunity;
    - iii) technical specification of the vaccines used, including matching with the circulating FMDV strains, and description of the licensing procedures in place;
    - iv) the proposed timeline for the transition to the use of vaccines fully compliant with the standards and methods described in the *Terrestrial Manual*;
- 7) provide an emergency preparedness and response plan to be implemented in case of *outbreaks*.



The Member Country's *official control programme* for FMD will be included in the list of programmes endorsed by the OIE only after the submitted evidence, based on the provisions of Article 1.6.11., has been accepted by the OIE. Retention on the list requires an annual update on the progress of the *official control programme* and information on significant changes concerning the points above. Changes in the epidemiological situation and other significant events should be reported to the OIE according to the requirements in Chapter 1.1.

The OIE may withdraw the endorsement of the *official control programme* if there is evidence of:

- non-compliance with the timelines or performance indicators of the programme; or
- significant problems with the performance of the *Veterinary Services*; or
- an increase in the incidence of FMD that cannot be addressed by the programme.

Article 8.7.40.

### General principles of surveillance

Articles 8.7.40. to 8.7.42. define the principles and provide a guide for the *surveillance* of FMD in accordance with Chapter 1.4. applicable to Member Countries seeking establishment, maintenance or recovery of freedom from FMD at the country, *zone* or *compartment* level or ~~Member Countries~~ seeking endorsement by the OIE of their *official control programme* for FMD, in accordance with Article 8.7.39. *Surveillance* aimed at identifying *disease* and FMDV *infection* or transmission should cover domestic and, where appropriate, *wildlife* species as indicated in point 2 of Article 8.7.1. within the country, zone or compartment.

#### 1. Early detection

A *surveillance* system in accordance with Chapter 1.4. should be the responsibility of the *Veterinary Authority* and should provide an early warning system to report suspected cases throughout the entire production, marketing and processing chain. A procedure should be in place for the rapid collection and transport of samples to a *laboratory* for FMD diagnosis. This requires that sampling kits and other equipment be available to those responsible for *surveillance*. Personnel responsible for *surveillance* should be able to call for seek assistance from a team with expertise in FMD diagnosis and control.

#### 2. Demonstration of freedom

The impact and epidemiology of FMD differ widely in different regions of the world and therefore it is inappropriate to provide specific recommendations for all situations. *Surveillance* strategies employed for demonstrating freedom from FMD in the country, *zone* or *compartment* at an acceptable level of confidence should be adapted to the local situation. For example, the approach to proving demonstrating freedom from FMD following an *outbreak* caused by a pig-adapted strain of FMDV should differ significantly from an application approach designed to prove demonstrate freedom from FMD for in a country or *zone* where African buffaloes (*Syncerus caffer*) provide a potential reservoir of *infection*.

Surveillance for FMD should be in the form of a continuing programme. Programmes to demonstrate no evidence of FMDV infection and transmission should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by the OIE or trading partners, or being excessively costly and logistically complicated.

The strategy and design of the *surveillance* programme will depend on the historical epidemiological circumstances including whether or not *vaccination* has been used.

A Member Country wishing to substantiate demonstrate FMD freedom where *vaccination* is not practised should show absence demonstrate no evidence of FMDV *infection*.



A Member Country wishing to substantiate demonstrate FMD freedom where *vaccination* is practised should show demonstrate that FMDV has not been transmitted in any susceptible populations. Within vaccinated populations, serological surveys to demonstrate the absence no evidence of FMDV transmission should target animals that are less likely to show vaccine-derived antibodies to nonstructural proteins, such as young animals vaccinated a limited number of times, or unvaccinated animals. In any unvaccinated subpopulation, surveillance should demonstrate no evidence Absence of FMDV *infection* should be demonstrated in any unvaccinated subpopulations.

*Surveillance* strategies employed for establishing and maintaining a *compartment* should identify the prevalence, distribution and characteristics of FMD outside the *compartment*.

### 3. OIE endorsed official control programme

*Surveillance* strategies employed in support of an OIE endorsed *official control programme* should show demonstrate evidence of the effectiveness of any *vaccination* used and of the ability to rapidly detect all FMD *outbreaks*.

Therefore considerable latitude is available to Member Countries to design and implement *surveillance* to establish that the whole territory or part of it is free from FMDV *infection* and transmission and to understand the epidemiology of FMD as part of the *official control programme*.

It is incumbent upon The Member Country to should submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors, including the role of *wildlife*, if appropriate, are identified and managed. This should include provision of scientifically based supporting data.

*Surveillance* for FMD should be in the form of a continuing programme. *Surveillance* programmes to prove the absence of FMDV *infection* and transmission should be carefully designed and implemented to avoid producing results that are insufficient to be accepted by the OIE or trading partners, or being excessively costly and logistically complicated.

### 4. Surveillance strategies

The strategy employed to establish the prevalence of FMDV *infection* or to substantiate freedom from FMDV *infection* or transmission may be based on randomised or targeted clinical investigation or sampling at an acceptable level of statistical confidence, as described in Articles 1.4.4. and 1.4.5. If an increased likelihood of *infection* in particular localities or species can be identified, targeted sampling may be appropriate. Clinical inspection may be targeted at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). The Member Country should justify the *surveillance* strategy chosen and the frequency of sampling as adequate to detect the presence of FMDV *infection* or transmission in accordance with Chapter 1.4. and the epidemiological situation.

The design of the sampling strategy should incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing should be adequate to detect *infection* or transmission if it were to occur at a predetermined minimum rate. The sample size and expected *disease* prevalence determine the level of confidence in the results of the survey. The Member Country should justify the choice of design prevalence and confidence level based on the objectives of *surveillance* and the prevailing or historical epidemiological situation, in accordance with Chapter 1.4.

### 5. Follow up of suspected cases and interpretation of results

An effective *surveillance* system will identify suspected cases that require immediate follow-up and investigation to confirm or exclude that the cause of the condition is FMDV. Samples should be taken and submitted for diagnostic testing, unless the suspected case can be confirmed or ruled out by epidemiological and clinical investigation. Details of the occurrence of suspected cases and how they were investigated and dealt with should be documented. This should include the results of diagnostic testing and the control measures to which the animals concerned were subjected during the investigation.

The sensitivity and specificity of the diagnostic tests employed, including the performance of confirmatory tests, are key factors in the design, sample size determination and interpretation of the



results obtained. The sensitivity and specificity of the tests used should be validated for the *vaccination* or *infection* history and production class of animals in the target population.

The *surveillance* design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There should be an effective procedure for following-up positives to determine with a high level of confidence, whether or not they are indicative of *infection* or transmission. This should involve supplementary tests and follow-up investigation to collect diagnostic material from the original *epidemiological unit* and *herds* which may be epidemiologically linked to it.

*Laboratory* results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral transmission includes but is not limited to:

- characterisation of the existing production systems;
- results of clinical *surveillance* of the suspects and their cohorts;
- description of number of, and protocol for, *vaccinations* performed in the area under assessment;
- biosecurity and history of the *establishments* with **positive** reactors;
- ~~– control of animal identification and movements;~~
- = identification and traceability of animals and control of their movements
- other parameters of regional significance in historic FMDV transmission.

## **6. Demonstration of population immunity**

Following ~~the use of~~ routine ~~and emergency~~ *vaccination*, evidence should be provided to **show demonstrate** the effectiveness of the *vaccination* programme such as adequate *vaccination* coverage and population immunity. This can help to reduce reliance on post-*vaccination* surveys for residual *infection* and transmission.

In designing serological surveys to estimate population immunity, blood sample collection should be stratified by age to take account of the number of *vaccinations* the animals have received. The interval between last *vaccination* and sampling depends upon the intended purpose. Sampling at one or two months after *vaccination* provides information on the efficiency of the *vaccination* programme, while sampling before or at the time of revaccination provides information on the duration of immunity. When multivalent vaccines are used, tests should be carried out to determine the antibody level at least for each serotype, if not for each antigen blended into the vaccine. The test cut-off for an acceptable level of antibody should be selected with reference to protective levels demonstrated by vaccine-challenge test results for the antigen concerned. Where the threat from circulating virus has been characterised as resulting from a field virus with significantly different antigenic properties from the vaccine virus, this should be taken into account when interpreting the protective effect of population immunity. Figures for population immunity should be quoted with reference to the total of susceptible animals in a given *subpopulation* and in relation to the subset of vaccinated animals.

The entire investigative process should be documented ~~as standard operating procedure~~ within the *surveillance* programme.

All the epidemiological information should be substantiated, and the results should be collated in the final report.

Article 8.7.41.

## **Methods of surveillance**

### **1. Clinical surveillance**

Farmers and workers who have day-to-day contact with livestock, as well as *veterinary para-professionals*, *veterinarians* and diagnosticians, should report promptly any suspicion of FMD. The *Veterinary Authority* should implement programmes to raise awareness among them.



Clinical *surveillance* requires close the physical examination of susceptible animals. Although significant emphasis is placed on the diagnostic value of mass serological screening, *surveillance* based on clinical inspection may provide a high level of confidence of detection of *disease* if a sufficient number of clinically susceptible animals is examined at an appropriate frequency and investigations are recorded and quantified.

Clinical examination and diagnostic testing should be applied to clarify the status of suspected cases detected by either of these complementary diagnostic approaches. Diagnostic testing may confirm clinical suspicion, while clinical *surveillance* may contribute to confirmation of positive laboratory test results. Clinical *surveillance* may be insufficient in *wildlife* and domestic species that usually do not show clinical signs or husbandry systems that do not permit sufficient observations. In such situations, serological surveillance should be used. Hunting, capture and non-invasive sampling and observation methods can be used to obtain information and diagnostic samples from *wildlife* species.

## 2. Virological surveillance

Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is mostly dependent upon clinical *surveillance* to provide samples. FMDV isolates should be sent regularly to an OIE Reference Laboratory.

Virological *surveillance* aims to:

- a) confirm clinically suspected cases;
- b) follow up positive serological results;
- c) characterise isolates for epidemiological studies and vaccine matching;
- d) monitor populations at risk for the presence and transmission of the virus.

## 3. Serological surveillance

Serological *surveillance* aims at to detecting antibodies resulting from *infection* or *vaccination* using nonstructural protein tests or structural protein tests.

Serological *surveillance* may be used to:

- a) estimate the prevalence or substantiate freedom from FMDV *infection* or transmission;
- b) monitor population immunity.

Serum collected for other purposes can be used for FMD *surveillance*, provided the principles of survey design described in this chapter are met.

The results of random or targeted serological surveys are important in providing reliable evidence of the FMD situation in a country, *zone* or *compartment*. It is therefore essential that the survey be thoroughly documented.

Article 8.7.42.

### **The use and interpretation of serological tests (see Figure 3)**

The selection and interpretation of serological tests should be considered in the context of the epidemiological situation. Test protocols, reagents, performance characteristics and validation of all tests used should be known. Where combinations of tests are used, the overall test system performance characteristics should also be known.

Animals infected with FMDV produce antibodies to both the structural proteins and the nonstructural proteins of the virus. Vaccinated animals produce antibodies mainly or entirely to the structural proteins of the virus depending upon vaccine purity. The structural protein tests are serotype specific and for optimal sensitivity one should select an antigen or virus closely related to the field strain expected. In unvaccinated populations, structural protein tests may be used to screen sera for evidence of FMDV *infection* or transmission or to detect the introduction of vaccinated animals. In vaccinated populations, structural protein tests may be used to monitor the serological response to the *vaccination*.

Nonstructural protein tests may be used to screen sera for evidence of *infection* or transmission of all serotypes of FMDV regardless of the *vaccination* status of the animals provided the vaccines comply with the standards of the *Terrestrial Manual* with respect to purity. However, although animals vaccinated and subsequently infected with FMDV develop antibodies to nonstructural proteins, the levels may be lower than



those found in infected animals that have not been vaccinated. To ensure that all animals that had contact with FMDV have seroconverted, it is recommended that for each *vaccination* area samples for nonstructural protein antibody testing are taken not earlier than 30 days after the last case and in any case not earlier than 30 days after the last *vaccination*.

Positive FMDV antibody test results can have four possible causes:

- a) *infection* with FMDV;
- b) *vaccination* against FMD;
- c) maternal antibodies (maternal antibodies in cattle are usually found only up to six months of age but in some individuals and in some other species, maternal antibodies can be detected for longer periods);
- d) non-specific reactivity of the serum in the tests used.

#### Procedure in case of positive test results:

The proportion and strength of seropositive reactors should be taken into account when deciding if they are laboratory confirmed reactors or further investigation and testing are required.

When false positive results are suspected, seropositive reactors should be retested in the *laboratory* using repeat and confirmatory tests. Tests used for confirmation should be of high diagnostic specificity to minimise false positive test **reactors results**. The diagnostic sensitivity of the confirmatory test should approach that of the screening test.

All *herds* with at least one *laboratory* confirmed reactor should be investigated. The investigation should examine all evidence, **including which may include** the results of virological tests **and of any further serological tests** that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were due to FMDV transmission, **and This investigation** should document the status for each positive *herd*. Epidemiological investigation should be continued concurrently.

Clustering of seropositive **reactions results within herds or within a region** should be investigated as it may reflect any of a series of events, including the demographics of the population sampled, vaccinal exposure or the presence of *infection* or transmission. As clustering may signal *infection* or transmission, the investigation of all instances should be incorporated in the survey design.

Paired serology can be used to identify FMDV transmission by demonstrating an increase in the number of seropositive animals or an increase in antibody titre at the second sampling.

The investigation should include the reactor animals, susceptible animals of the same *epidemiological unit* and susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals. The animals sampled should remain in the *establishment* pending test results, should be clearly identifiable, accessible and should not be vaccinated during the investigations, so that they can be retested after an appropriate period of time. Following clinical examination, a second sample should be taken, **after an appropriate time has lapsed**, from the animals tested in the initial survey with emphasis on animals in direct contact with the reactors, **after an appropriate time has lapsed**. If the animals are not individually identified, a new serological survey should be carried out in the *establishments* after an appropriate time, repeating the application of the primary survey design. If FMDV is not circulating, the magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample.



In some circumstances, unvaccinated sentinel animals may also be used. These can be young, unvaccinated animals from unvaccinated dams or animals in which maternally conferred immunity has lapsed and preferably of the same species as in the positive sampling units. If other susceptible, unvaccinated animals are present, they could act as sentinels to provide additional serological evidence. The sentinels should be kept in close contact with the animals of the *epidemiological unit* under investigation for at least two *incubation periods* and should remain serologically negative if FMDV is not circulating.

#### Follow-up of field and laboratory findings:

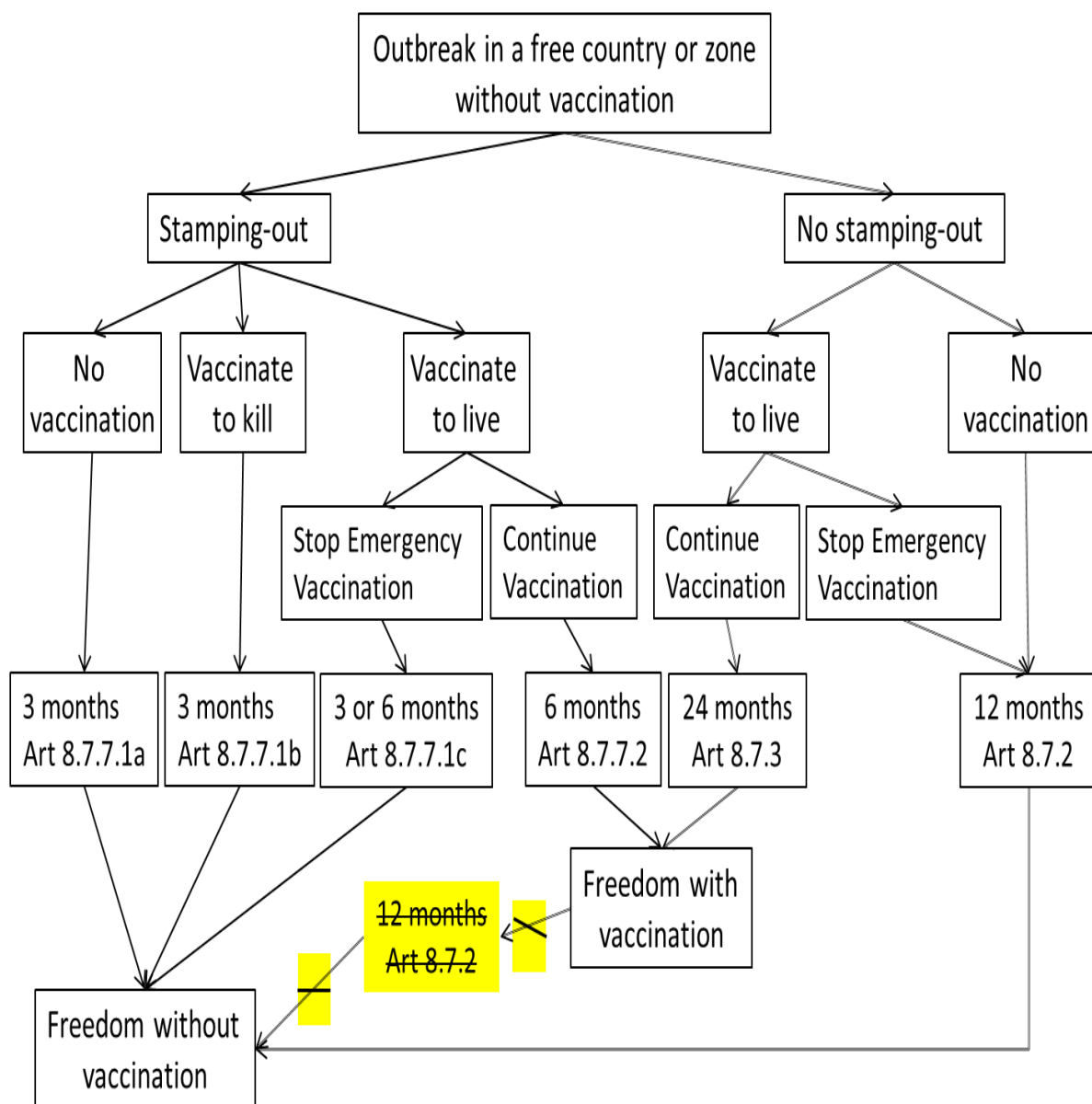
If transmission is preven demonstrated, then an *outbreak* is declared.

The significance of small numbers of seropositive animals in the absence of current FMDV transmission is difficult to determine. Such findings may be an indication of past *infection* followed by recovery or by the development of a carrier state, in ruminants, or due to non-specific serological reactions. Antibodies to nonstructural proteins may be induced by repeated *vaccination* with vaccines that do not comply with the requirements for purity. However, the use of such vaccines is not permissible in countries or *zones* applying for an official status. In the absence of evidence of FMDV *infection* and transmission, such findings do not warrant the declaration of a new *outbreak* and the follow-up investigations may be considered complete.

However, if the number of seropositive animals is greater than the number of false positive results expected from the specificity of the diagnostic tests used ~~non-specific test system findings expected~~, susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animals should be investigated further.



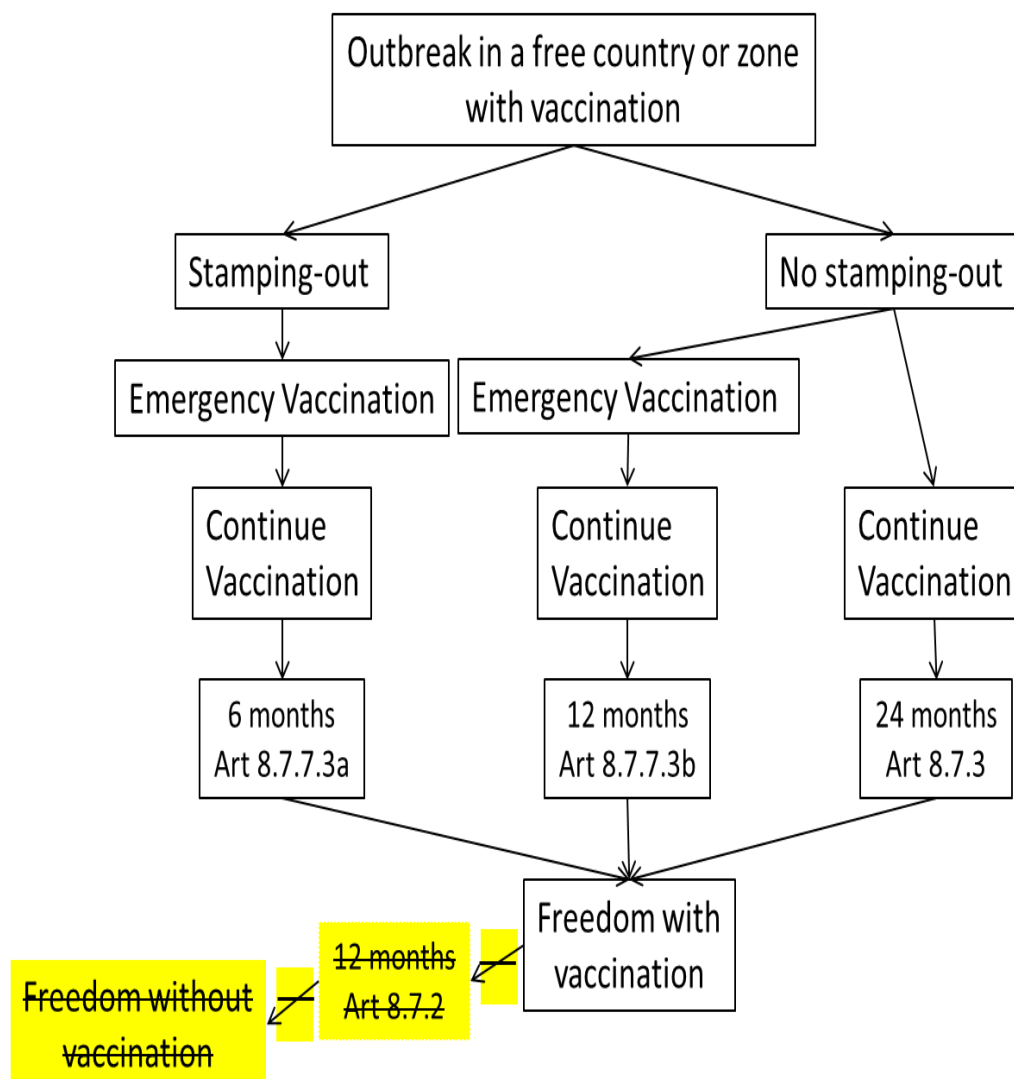
**Figure 1. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak in a free country or zone where vaccination is not practised**



*Waiting periods are minima depending upon outcome of surveillance specified in respective Articles. If there are multiple waiting periods because of different control measures, the longest applies.*



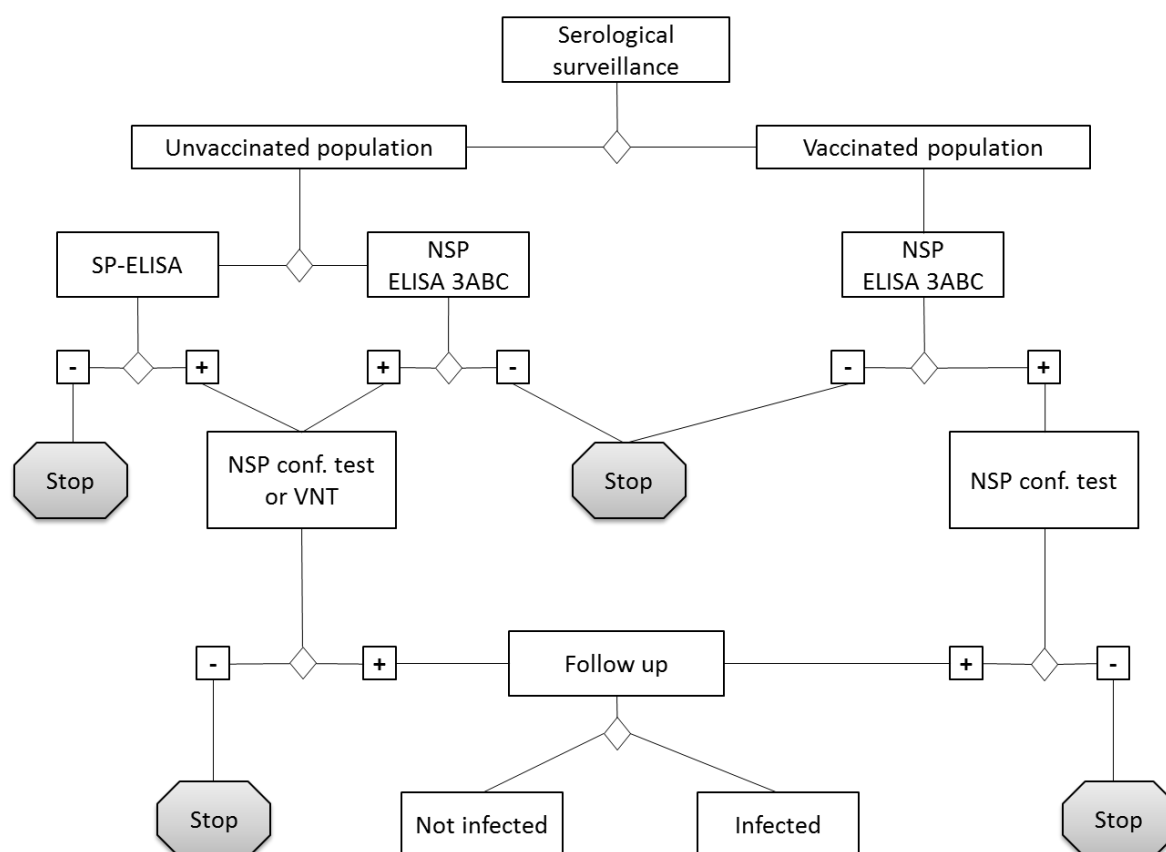
**Figure 2. Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status after an outbreak in a free country or zone where vaccination is practised**



*Waiting periods are minima depending upon outcome of surveillance specified in respective Articles .  
If there are multiple waiting periods because of different control measures, the longest applies.*



**Figure 3. Schematic representation of laboratory tests for determining evidence of FMDV infection by means of serological surveys**



Abbreviations and acronyms:

ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Nonstructural proteins of foot and mouth disease virus
3ABC	NSP antibody test
SP	Structural protein of foot and mouth disease virus



## CHAPTER 1.6.

PROCEDURES FOR SELF DECLARATION AND FOR  
OFFICIAL RECOGNITION BY THE OIE

## Article 1.6.1.

**General principles**

Member Countries may wish to make a self declaration as to the freedom of a country, *zone* or *compartment* from an OIE *listed disease*. The Member Country may inform the OIE of its claimed status and the OIE may publish the claim. Publication does not imply endorsement of the claim. The OIE does not publish self declaration for bovine spongiform encephalopathy (BSE), foot and mouth disease (FMD), contagious bovine pleuropneumonia (CBPP), African horse sickness (AHS), peste des petits ruminants (PPR) and classical swine fever (CSF).

Member Countries may request official recognition by the OIE as to:

- 1) the risk status of a country or *zone* with regard to BSE;
- 2) the freedom of a country or *zone* from FMD, with or without *vaccination*;
- 3) the freedom of a country or *zone* from CBPP;
- 4) the freedom of a country or *zone* from AHS;
- 5) the freedom of a country or *zone* from PPR;
- 6) the freedom of a country or *zone* from CSF.

The OIE does not grant official recognition for other *diseases*.

In these cases, Member Countries should present documentation setting out the compliance of the *Veterinary Services* of the applicant country or *zone* with the provisions of Chapters 1.1., 3.1. and 3.2. of the *Terrestrial Code* and with the provisions of the relevant *disease* chapters in the *Terrestrial Code* and the *Terrestrial Manual*.

When requesting official recognition of disease status, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested (as appropriate) in Articles 1.6.5. (for BSE), 1.6.6. (for FMD), 1.6.7. (for CBPP), 1.6.8. (for AHS), 1.6.9. (for PPR) or 1.6.10. (for CSF).

The OIE framework for the official recognition and maintenance of disease status is described in Resolution N° XXX (administrative procedures) and Resolution N° XXVI (financial obligations) adopted during the 81<sup>st</sup> General Session in May 2013.

## Article 1.6.2.

**Endorsement by the OIE of an official control programme for FMD**

Member Countries may wish to request an endorsement by the OIE of their *official control programme* for FMD.

When requesting endorsement by the OIE of an *official control programme* for FMD, the Member Country should submit to the OIE Scientific and Technical Department a dossier providing the information requested in Article 1.6.11.



[Article 1.6.3.]

[Article 1.6.4.]

[Article 1.6.5.]

Article 1.6.6.

## Questionnaires on FMD

### FMD FREE COUNTRY WHERE VACCINATION IS NOT PRACTISED

Report of a Member Country which applies for recognition of status,  
under Chapter 8.7. of the *Terrestrial Code*,  
as a FMD free country not practising vaccination

Please Address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

#### 1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

#### 2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *Veterinary Services* supervise, control and maintain all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

#### 3. FMD eradication

- a) History. Provide a description of the FMD history in the country, date of first detection, origin of *infection*, date of eradication (date of last case), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, *modified stamping-out policy*, zoning).
- c) Vaccines and *vaccination*. Was FMD vaccine ever used? If so, when was the last *vaccination* carried out? When was vaccination formally prohibited? What species were vaccinated? What was the fate of these animals?

In addition, if vaccination was conducted during the past two years, provide a description and justification of the vaccination strategy, including the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the vaccination of animals was certified or reported and the records maintained. Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.

- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.



- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements detected.

#### 4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the names of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
  - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
  - ii) Give details of performance in inter-laboratory proficiency tests.
  - iii) Provide details on the handling of live virus
  - iv) Biosecurity measures applied.
  - v) Details of the type of tests undertaken and their performance for their applied use (specificity/ and sensitivity).
  - vi) Laboratory capacity in processing tests and samples.

#### 5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. to 8.7.42. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).
- b) Serological *surveillance*. Have serological surveys been conducted to demonstrate freedom from *infection*? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.



- d) *Wildlife* demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?
- e) *Slaughterhouses* and markets or events associated with the congregation of FMD-susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

## 6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.
- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and *surveillance* measures.
- c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or *zone* of origin, species **and volume** and quantity.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
  - animals,
  - genetic material (semen and embryos),
  - animal products,
  - *veterinary medicinal products* (i.e. biologics),
  - other **FMD-risk** materials **at risk of being contaminated with FMDV** (e.g. stock feed and animal bedding).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on **detected** illegal imports **detected**.
- d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.

## 7. Contingency planning and outbreak response programmes



- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. livestock standstills)?
- c) In the event of a FMD *outbreak*:
  - i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;
  - ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
  - iii) indicate the control or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial *slaughter* or *vaccination*, methods of disposal of carcasses and other contaminated products and materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
  - iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serological surveillance programmes;
  - v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

#### 8. Compliance with the *Terrestrial Code*

- a) In addition to the documentary evidence that the provisions of Article 8.7.2. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:
  - i) there has been no *outbreak* of FMD during the past 12 months;
  - ii) no evidence of FMDV *infection* has been found during the past 12 months;
  - iii) no *vaccination* against FMD has been carried out during the past 12 months,
- b) and should confirm that since the cessation of *vaccination* no animals vaccinated against FMD have been imported.

#### 9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.7., 8.7.2.1, 8.7.2.3 and 8.7.2.4. of the *Terrestrial Code* and provide information as specified in sections 1 – 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).



### FMD FREE COUNTRY WHERE VACCINATION IS PRACTISED

Report of a Member Country which applies for recognition of status,  
under Chapter 8.7. of the *Terrestrial Code*,  
as a FMD free country practising vaccination

Please Address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

#### 1. Introduction

- a) Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to FMD dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of *disease*. Provide a map identifying the factors above.
- b) Livestock industry. Provide a general description of the livestock industry in the country.

#### 2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *Veterinary Services* supervise, control and maintain all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

#### 3. FMD eradication

- a) History. Provide a description of the FMD history in the country, date of first detection, origin of *infection*, date of eradication (date of last case), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated (e.g. *stamping-out policy*, *modified stamping-out policy*, zoning).
- c) Vaccines and *vaccination*. Provide a description and justification of the *vaccination* strategy, including, the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained, the date on which the last *vaccination* was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. *vaccination* coverage, serological surveillance, etc). Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability, including *vaccination* data. How are animal movements controlled in the country? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements detected.

#### 4. FMD diagnosis



Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

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  - ii) Give details of performance in inter-laboratory proficiency tests.
  - iii) Provide details on the handling of live virus
  - iv) Biosecurity measures applied.
  - v) Details of the type of tests undertaken and their performance for their applied use (specificity and sensitivity).
  - vi) Laboratory capacity in processing tests and samples.

#### 5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. to 8.7.42. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).
- b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*, in particular applying the provisions of Article 8.7.42. If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are **wildlife** susceptible **wildlife** species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) *Wildlife* demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?
- e) *Slaughterhouses*, markets and events associated with the congregation of FMD-susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?



## 6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.
- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so provide information on the extent of the practice, and describe controls and *surveillance* measures.
- c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or *zone* of origin, species **and volume** and quantity

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
  - ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
  - iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
    - animals,
    - genetic material (semen and embryos),
    - animal products,
    - *veterinary medicinal products* (i.e. biologics),
    - other **FMD risk materials at risk of being contaminated with FMDV (e.g. stock feed and animal bedding).**
  - iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.
- d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.



## 7. Contingency planning and outbreak response programmes

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. livestock standstills)?
- c) In the event of a FMD *outbreak*:
  - i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;
  - ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
  - iii) indicate the control or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial *slaughter* or *vaccination*, methods of disposal of carcasses and other contaminated products or materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
  - iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serosurveillance programmes;
  - v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

## 8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.7.3. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating that there has been no *outbreak* of FMD for the past two years and no evidence of FMDV transmission for the past 12 months, with documented evidence that:

- a) *surveillance* for FMD and FMDV transmission in accordance with Articles 8.7.40. to 8.7.42. and is in operation, and that regulatory measures for the prevention and control of FMD have been implemented;
- b) routine *vaccination* is carried out for the purpose of the prevention of FMD;
- c) the vaccine used complies with the standards described in the *Terrestrial Manual*.

## 9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.7., 8.7.3.1, 8.7.3.3 and 8.7.3.4. of the *Terrestrial Code* and provide information as specified in sections 1 – 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).



### FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED

Report of a Member Country which applies for recognition of status,  
under Chapter 8.7. of the *Terrestrial Code*,  
as a FMD free zone not practising vaccination

Please Address concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

#### 1. Introduction

- a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

#### 2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *Veterinary Services* supervise, control and maintain all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

#### 3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last case), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, *modified stamping-out policy*).
- c) Vaccines and vaccination. **#**
  - i) Was vaccination is ever used in the *zone*? If so, when was the last vaccination carried out? When was vaccination formally prohibited? What species were vaccinated? What was the fate of those animals? rest of the country,
  - ii) In addition, if vaccination was conducted during the past two years, provide a description and justification of the vaccination strategy, including, the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the vaccination of animals was certified or reported and the records maintained, the date on which the last vaccination was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. vaccination coverage, serosurveillance, etc). Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.
  - iii) If vaccination continues to be used in the rest of the country, give details on the post-vaccination monitoring programme.
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.



- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.7.10. are applied? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements

#### 4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the names of and the arrangements with the laboratory(ies) samples are sent to. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed, the follow-up procedures and the time frame for obtaining results.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
  - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
  - ii) Give details of performance in inter-laboratory proficiency tests.
  - iii) Provide details on the handling of live virus
  - iv) Biosecurity measures applied.
  - v) Details of the type of tests undertaken and their performance for their applied use (specificity and sensitivity).
  - vi) Laboratory capacity in processing tests and samples.

#### 5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. to 8.7.42. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).
- b) Serological *surveillance*. Have serological surveys been conducted to demonstrate freedom from *infection*? If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.
- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.



- d) *Wildlife* demographics. What susceptible species are present in the country and the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?
- e) *Slaughterhouses*, markets and events associated with the congregation of FMD-susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

## 6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* without *vaccination* is situated in a FMD infected country or borders an infected country or *zone*, describe the animal health biosecurity measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.

- c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such *animals* and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or *zone* of origin, species and volume and quantity.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
  - animals,
  - genetic material (semen and embryos),
  - animal products,
  - *veterinary medicinal products* (i.e. biologics),
  - other FMD risk materials at risk of being contaminated with FMDV (e.g. stock feed and animal bedding).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports detected.



- d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.

## 7. Contingency planning and outbreak response programmes

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. livestock standstills)?
- c) In the event of a FMD *outbreak*:
- i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;
  - ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
  - iii) indicate the control or eradication procedures (e.g. *vaccination*, *stamping-out policy*, partial *slaughter* or *vaccination*, methods of disposal of carcasses and other contaminated products or materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
  - iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serosurveillance programmes;
  - v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

## 8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.7.4. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

- a) there has been no *outbreak* of FMD during the past 12 months;
- b) no evidence of FMDV *infection* has been found during the past 12 months;
- c) no *vaccination* against FMD has been carried out during the past 12 months;
- d) no vaccinated animal has been introduced into the *zone* since the cessation of *vaccination*, except in accordance with Article 8.7.10.

## 9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.7., 8.7.2.1, 8.7.2.3 and 8.7.2.4. of the *Terrestrial Code* and provide information as specified in sections 1 – 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

**FMD FREE ZONE WHERE VACCINATION IS PRACTISED**  
Report of a Member Country which applies for recognition of status,  
under Chapter 8.7. of the *Terrestrial Code*,  
as a FMD free zone practising vaccination

Please **Address** concisely the following topics. National regulations and laws and Veterinary Administration directives may be referred to and annexed as appropriate in one of the OIE official languages.

## 1. Introduction



- a) Geographical factors. Provide a general description of the country and the *zone* including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that although may not be adjacent share a link for the potential introduction of *disease*. The boundaries of the *zone* must be clearly defined, including a *protection zone* if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zone*.
- b) Livestock industry. Provide a general description of the livestock industry in the country and the *zone*.

## 2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to FMD.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Service* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *Veterinary Services* supervise, control and maintain all FMD related activities. Provide maps and tables wherever possible.
- c) Role of farmers, industry and other relevant groups in FMD *surveillance* and control (include a description of training and awareness programmes on FMD).
- d) Role of private veterinary profession in FMD *surveillance* and control.

## 3. FMD eradication

- a) History. Provide a description of the FMD history in the country and *zone*, provide date of first detection, origin of *infection*, date of eradication in the *zone* (date of last case), types and subtypes present.
- b) Strategy. Describe how FMD was controlled and eradicated in the *zone* (e.g. *stamping-out policy*, *modified stamping-out policy*).
- c) Vaccines and *vaccination*. provide a description and justification of the *vaccination* strategy, including, the selection of vaccine strain, potency and type, purity, details of any vaccine matching performed, the animal species vaccinated, identification of vaccinated animals, the way in which the *vaccination* of animals was certified or reported and the records maintained, the date on which the last *vaccination* was performed, and the disposition of vaccinated animals (e.g. removed from or retained in the population). Provide evidence to show its effectiveness (e.g. *vaccination* coverage, serosurveillance, etc). Also provide evidence that the vaccine used complies with Chapter 2.1.5. of the *Terrestrial Manual*.
- d) Legislation, organisation and implementation of the FMD eradication campaign. Provide a description of the organisational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.



- e) *Animal identification* and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of *animal identification*, *herd* registration and traceability, including *vaccination* data. How are animal movements controlled in and between *zones* of the same or different status, in particular if the provisions of the *Terrestrial Code* in Article 8.7.10. are applied? Provide evidence on the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe the action taken when an illegal movement is detected. Provide information on detected illegal movements

#### 4. FMD diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the names of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. Indicate the laboratory(ies) where samples originating from the *zone* are diagnosed.
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points.
  - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or planned for, the laboratory system.
  - ii) Give details of performance in inter-laboratory proficiency tests.
  - iii) Provide details on the handling of live virus
  - iv) Biosecurity measures applied.
  - v) Details of the type of tests undertaken and their performance for their applied use (specificity and sensitivity).
  - vi) Laboratory capacity in processing tests and samples.

#### 5. FMD surveillance

Provide documentary evidence that *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40. to 8.7.42. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Clinical suspicion. What are the criteria for raising a suspicion of FMD? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspected cases, the number of samples tested for FMDV, species, type of sample, testing methods and results (including differential diagnosis).
- b) *Surveillance*. Are serological and virological surveys conducted to demonstrate freedom from *infection*?, in particular applying the provisions of Article 8.7.42 If so, provide detailed information on the survey design (target population, design prevalence, confidence level, sample size, stratification, sampling methods and diagnostic tests used). How frequently are they conducted? Are *wildlife* susceptible species included in serological surveys? Provide a summary table indicating, for the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide details on follow-up actions taken on all suspicious and positive results. Provide criteria for selection of populations for targeted *surveillance* based on the risk and numbers of animals examined and samples tested. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators.



- c) Livestock demographics and economics. What is the susceptible animal population by species and production systems in the country and the *zone*? How many *herds*, *flocks*, etc. of each susceptible species are in the country? How are they distributed (e.g. *herd* density, etc.)? Provide tables and maps as appropriate.
- d) *Wildlife* demographics. What susceptible species are present in the country and in the *zone*? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and *wildlife* susceptible species?
- e) *Slaughterhouses*, markets and events associated with the congregation of FMD-susceptible livestock (e.g. fairs, shows, competitions). Where are the major livestock marketing or collection centres? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions?

## 6. FMD prevention

- a) Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries and *zones* that should be taken into account (e.g. size, distance from adjacent border to affected *herds* or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*.

If the FMD free *zone* with *vaccination* is situated in a FMD infected country or borders an infected country or *zone*, describe the **animal health biosecurity** measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers.

- b) Are there controls in place for the feeding of swill containing animal products to pigs? If so, provide information on the extent of the practice, and describe controls and *surveillance* measures.
- c) Import control procedures

From what countries or *zones* does the country authorise the import of susceptible animals or their products into a free *zone*? What criteria are applied to approve such countries or *zones*? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying the country or *zone* of origin, the species **and the volume** and quantity.

- i) Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of and the disposal locations.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country or their final destination, concerning the import and follow-up of the following:
  - animals,
  - genetic material (semen and embryos),
  - animal products,
  - *veterinary medicinal products* (i.e. biologics),
  - other **FMD-risk** materials **at risk of being contaminated with FMDV** (e.g. **stock feed and animal bedding**).
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on **detected** illegal imports **detected**.



- d) Describe and justify the corrective actions that have been implemented to prevent future FMD outbreaks in response to any past disease incursions.

## 7. Contingency planning and outbreak response programmes

- a) Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases (e.g. livestock standstills)?
- c) In the event of a FMD *outbreak*:
  - i) indicate the sampling and testing procedures to be used to identify and confirm presence of the causative agent;
  - ii) describe the actions to be taken to report and control the disease situation in and around any *establishments* found to be infected with FMD;
  - iii) indicate the control or eradication procedures (e.g. *vaccination, stamping-out policy, partial slaughter or vaccination*, methods of disposal of carcasses and other contaminated products or materials, decontamination, etc.) that would be taken. Include information on access to antigen and vaccine banks;
  - iv) describe the procedures to be used to confirm successful control or eradication, including any restocking provisions, sentinel animal and serosurveillance programmes;
  - v) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable.

## 8. Compliance with the *Terrestrial Code*

In addition to the documentary evidence that the provisions of Article 8.7.5. are properly implemented and supervised, the Delegate of the Member Country must submit a declaration indicating:

- a) that there has been no *outbreak* of FMD for the past two years,
- b) no evidence of FMDV transmission for the past 12 months,
- c) *surveillance* for FMD and FMDV transmission in accordance with Articles 8.7.40 to 8.7.42. is in operation.

## 9. Recovery of status

Member Countries applying for recovery of status should comply with the provisions of Articles 8.7.7., 8.7.3.1, 8.7.3.3 and 8.7.3.4. of the *Terrestrial Code* and provide information as specified in sections 1 – 7 (inclusive) of this questionnaire. Particular emphasis should be given to FMD eradication (section 3.), FMD diagnosis (section 4.), FMD serological surveillance (section 5.b.), FMD prevention (section 6.) and contingency planning and outbreak response programmes (section 7.).

[Article 1.6.7.]

[Article 1.6.8.]

[Article 1.6.9.]

[Article 1.6.10.]



## Questionnaire on FMD

**COUNTRY WITH AN OIE ENDORSED OFFICIAL CONTROL PROGRAMME FOR FMD**

Report of a Member Country which applies for the OIE endorsement

of its official control programme for FMD

under Chapter 8.7. of the *Terrestrial Code*

Please Address concisely the following topics. National laws, regulations and *Veterinary Authority* directives may be referred to and annexed as appropriate in one of the OIE official languages.

1. Introduction

- a) Provide a general description of geographical factors in the country and *zones*, including physical, geographical and other factors that are relevant to FMD dissemination, countries or *zones* sharing common borders and other countries or *zones* that, although not adjacent, present a *risk* for the introduction of *disease*.
- b) If the endorsed plan is gradually implemented to specific parts of the country, the boundaries of the *zones* should be clearly defined, including the *protection zone*, if applied. Provide a digitalised, geo-referenced map with a precise text description of the geographical boundaries of the *zones*.
- c) Provide a general description of the livestock industry in the country and any *zones*.

2. Veterinary system

- a) Legislation. Provide a list and summary of all relevant veterinary legislations in relation to the FMD control programme.
- b) *Veterinary Services*. Provide documentation on the compliance of the *Veterinary Services* of the country with the provisions of Chapters 3.1. and 3.2. of the *Terrestrial Code* and Article 1.1.3. of the *Terrestrial Code* and describe how the *Veterinary Services* supervise, control and maintain all FMD related activities in the country and any *zones*. Provide maps and tables wherever possible.
- c) Provide a description on the involvement and the participation of industry, producers, farmers, including subsistence and small scale producers, community animal health workers and the role of the private veterinary profession in FMD *surveillance* and control. Include a description of training and awareness programmes on FMD.
- d) Provide information on any OIE PVS evaluation of the country and follow-up steps within the PVS Pathway.
- e) Provide evidence that the legal framework and budget ensure that control and surveillance activities are implemented in an effective and sustainable way.

3. FMD control

- a) Provide a description of the FMD history in the country and any *zones*, including date of first detection, origin of *infection*, date of implementation of the control programme in the country and any *zones*, and types and subtypes of the FMDV present.
- b) Describe the general epidemiology of FMD in the country and the surrounding countries or *zones* highlighting the current knowledge and gaps.
- c) Describe how FMD is controlled in the country or any *zones*.
- d) Provide a description of the legislation, organisation and implementation of the FMD control programme. Indicate if detailed operational guidelines exist and give a brief summary.



- e) Provide information on what types of vaccines are used and which species are vaccinated. Provide information on the licensing process of the vaccines used. Describe the *vaccination* programme in the country and in any *zones*, including records kept, and provide evidence to show its effectiveness, such as *vaccination* coverage, population immunity, etc. Provide details on the studies carried out to determine the population immunity, including the study design.
- f) Provide a description of the methods of *animal identification* (at the individual or group level), *herd* registration and traceability; and how the movements of animals and products are assessed and controlled, including movement of infected animals to *slaughter*. Describe the effectiveness of *animal identification* and movement controls. Please provide information on pastoralism, transhumance and related paths of movement. Describe measures to prevent introduction of FMDV from neighbouring countries or *zones* and through trade.
- g) Provide evidence of the impact of the control measures already implemented in the event of outbreaks on the reduction of distribution and numbers of outbreaks. If possible, provide information on primary and secondary outbreaks.

#### 4. FMD surveillance

Provide documentary evidence on whether *surveillance* for FMD in the country complies with the provisions of Articles 8.7.40 to 8.7.42. of the *Terrestrial Code* and Chapter 2.1.5. of the *Terrestrial Manual*. In particular, the following points should be addressed:

- a) Describe the criteria for raising a suspicion of FMD and the procedure to notify (by whom and to whom) and what penalties are involved for failure to report.
- b) Describe how clinical *surveillance* is conducted, including which levels of the livestock production system are included in clinical *surveillance*, such as farms, markets, fairs, *slaughterhouse*, check points, etc. Provide criteria for selection of populations for targeted *surveillance* and numbers of animals examined and samples tested in diagnostic laboratories. Provide details on the methods applied for monitoring the performance of the *surveillance* system including indicators. Explain whether serological and virological surveys are conducted and, if so, how frequently and for what purpose.
- c) Provide a summary table indicating, for at least the past two years, the number of samples tested for FMD and FMDV, species, type of sample, testing methods and results (including differential diagnosis). Provide procedural details on follow-up actions taken on suspicious and positive results.
- d) Provide information on livestock demographics and economics, including the susceptible animal population by species and production systems in the country and the *zone*. Identify how many *herds*, *flocks*, etc. of each susceptible species are in the country and how they are distributed, such as *herd* density, etc. Provide tables and maps as appropriate.
- e) Provide information on the demographics and migration patterns of FMD susceptible *wildlife* species, including which susceptible species are present in the country and any *zones*. Provide estimates of population sizes and geographic distribution. Identify whether susceptible *wildlife* are included in *surveillance*. Identify the measures in place to prevent contact between domestic and susceptible *wildlife*.
- f) Identify the livestock slaughter, marketing and collection centres. Provide information on the patterns of livestock movement within the country, including how animals are transported and handled during these transactions.



- g) Provide information on circulating strains and risk in different husbandry systems, and provide evidence that targeted studies are implemented to address gaps (e.g. targeted serological surveys, active surveillance, participatory epidemiology studies, risk assessments etc) and that the acquired knowledge assists in more effective implementation of control measures.
- h) Provide evidence that surveys are carried out to assess *vaccination* coverage and population immunity of the target populations, show laboratory evidence that the vaccine used is appropriate for circulating strains of virus, show analysis of surveillance data to assess the change in FMD prevalence over time in the target populations, assess the control measures (cost effectiveness, degree of implementation, impact), provide information on outcomes of outbreak investigations including outbreaks that have occurred despite control measures, documented inspections showing compliance with biosecurity and hygiene requirements.

## 5. FMD laboratory diagnosis

Provide documentary evidence that the provisions in Chapters 1.1.2., 1.1.3. and 2.1.5. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- a) Is FMD laboratory diagnosis carried out in the country? If so, provide a list of laboratories approved by the competent authority to diagnose FMD. If not, provide the names of and the arrangements with the laboratory(ies) samples are sent to, the follow-up procedures and the time frame for obtaining results. If applicable, indicate the laboratory(ies) where samples originating from any *zone* are diagnosed. Is there regular submission of samples from the country or *zone* to a laboratory that carries out diagnosis and further characterisation of strains in accordance with the standards and methods described in the *Terrestrial Manual*?
- b) Provide an overview of the FMD approved laboratories, in particular to address the following points:
  - i) Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO, etc. that exist in, or are planned for, the laboratory system.
  - ii) Give details on participation in inter-laboratory validation tests (ring tests).
  - iii) Is live virus handled?
  - iv) Biosecurity measures applied.
  - v) Details of the type of tests undertaken.

## 6. FMD prevention

Describe the procedures in place to prevent the introduction of FMD into the country. In particular provide details on:

- a) Coordination with neighbouring countries, trading partners and other countries within the same region. Identify relevant factors about the adjacent countries and *zones* that should be taken into account such as size, distance from adjacent borders to affected *herds* or animals, *surveillance* carried in adjacent countries. Describe coordination, collaboration and information sharing activities with neighbouring countries and *zones*. Describe the measures implemented to effectively prevent the introduction of the agent, taking into consideration physical or geographical barriers. Describe the measures implemented to prevent the propagation of the agent within the country or *zone* and through trade. Provide evidence that measures are in place at markets to reduce transmission of FMD such as enhancing awareness of FMD transmission mechanisms and behaviours that can interrupt transmission, implementation of good biosecurity practices, hygiene, cleaning and disinfection routines at critical points all along the production and marketing networks (typically where animals are being moved, and marketed through the country or region).
- b) What measures are taken to limit access of susceptible domestic, *feral* and *wild* animals to waste products of animal origin? Are there controls in place for the feeding of swill containing animal



products to pigs? If so provide information on the extent of the practice, and describe controls and *surveillance* measures.

- c) Provide information on countries or *zones* from which the country authorises the import of susceptible animals or their products into the country or *zone*. Describe the criteria applied to approve such countries or *zones*, the controls applied on entry of such animals and products, and subsequent internal movement. Describe the import conditions and test procedures required. Advise whether imported animals of susceptible species are required to undergo a quarantine or isolation period and, if so, the duration and location of quarantine. Advise whether import permits and health certificates are required. Describe any other procedures used. Provide summary statistics on imports of susceptible animals and their products for at least the past two years, specifying country or *zone* of origin, the species and the number or volume. Provide evidence that the import policy and the improved border controls have contributed to reducing the number of outbreaks or that outbreaks are not related to imports or transboundary movements of domestic animals.
- i) Provide a map with the number and location of ports, airports and land crossings. Advise whether the service responsible for import controls is part of the official services, or if it is an independent body. If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central *Veterinary Services*. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.
- ii) Provide a description on the methods used for the safe disposal of waste food from international traffic, who is responsible to supervise this and provide a summary, for the past two years, of the quantity disposed of.
- iii) Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and their final destination, concerning the import and follow up of the following:
- animals,
  - genetic material (semen and embryos),
  - animal products,
  - *veterinary medicinal products*, i.e. biologics,
  - other livestock related goods potentially contaminated with FMDV including bedding, litter and feeds.
- iv) Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports detected, if available.

## 7. Control measures and emergency response

- a) Give details of any written guidelines, including emergency response plans, available to the *Veterinary Services* for dealing with suspected or confirmed *outbreaks* of FMD.
- b) Advise whether quarantine is imposed on premises with suspicious cases, pending final diagnosis and any other procedures followed in respect of suspicious cases.
- c) In the event of a FMD *outbreak*:
- i) provide a detailed description of procedures that are followed in case of an *outbreak* including forward and backward tracing;
  - ii) indicate the sampling and testing procedures used to identify and confirm presence of the causative agent;
  - iii) describe the actions taken to control the disease situation in and around any *establishments* found to be infected with FMD;
  - iv) indicate the control or eradication procedures, such as *vaccination*, *stamping-out policy*, *partial slaughter* or *vaccination*, including *vaccination* delivery and cold chain, movement



control, control of *wildlife*, pastured livestock and livestock as pets, control of the livestock waste, campaign to promote awareness of farmers, etc. that would be taken;

- v) describe the procedures used to confirm that an *outbreak* has been successfully controlled or eradicated, including any restrictions on restocking;
- vi) give details of any compensation payments made available to farmers, etc. when animals are slaughtered for *disease* control or eradication purposes and their prescribed timetable;
- vii) describe how control efforts, including *vaccination* and biosecurity measures, have been targeted at critical risk control points.

#### 8. Official control programme for FMD submitted for OIE endorsement

Submit a detailed plan on the measures, in addition to those described in point 3, for the control and eventual eradication of FMD in the Member Country, including:

- a) objectives,
- b) expected status to be achieved,
- c) timelines of the control programme,
- d) performance indicators and methods for their measurement and verification, including the progressive reduction in outbreak incidence towards elimination of FMDV transmission in all susceptible livestock in at least one *zone* of the country,
- e) description of the funding for the control programme and annual budgets for its duration,
- f) details, if applicable, on a proposed timeline for the transition to the use of vaccines, which are fully compliant with in the *Terrestrial Manual* in order to enable demonstration of absence no evidence of FMDV transmission.

#### 9. Recovery of official endorsement of the national FMD control programme

Member Countries applying for recovery of the official endorsement of the national FMD control programme should provide updated information in compliance with the provisions of Article 8.7.39. of the *Terrestrial Code*.